Federal Communications Commission
Washington, D.C. 20554

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DA 10-815

Small Entity Compliance Guide

Medical Device Radiocommunication Service

Report and Order
FCC 09-23
ET Docket Nos. 06-135, 05-213, 03-92
RM-11271
Released: March 20, 2009

This Guide is prepared in accordance with the requirements of Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It is intended to help small entities—small businesses, small organizations (non-profits), and small governmental jurisdictions—comply with the new rules adopted in the above-referenced FCC rulemaking docket(s). This Guide is not intended to replace the rules and, therefore, final authority rests solely with the rules. Although we have attempted to cover all parts of the rules that might be especially important to small entities, the coverage may not be exhaustive. This Guide may, perhaps, not apply in a particular situation based upon the circumstances, and the FCC retains the discretion to adopt approaches on a case-by-case basis that may differ from this Guide, where appropriate. Any decisions regarding a particular small entity will be based on the statute and regulations.

In any civil or administrative action against a small entity for a violation of rules, the content of the Small Entity Compliance Guide may be considered as evidence of the reasonableness or appropriateness of proposed fines, penalties or damages. Interested parties are free to file comments regarding this Guide and the appropriateness of its application to a particular situation; the FCC will consider whether the recommendations or interpretations in the Guide are appropriate in that situation. The FCC may decide to revise this Guide without public notice to reflect changes in the FCC's approach to implementing a rule, or to clarify or update the text of the Guide. Direct your comments and recommendations, or calls for further assistance, to the FCC's Consumer Center:

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1. Objectives of the Proceeding

In the Report and Order in this proceeding the Commission established a new Medical Device Radiocommunication Service (MedRadio Service) under Part 95 of the Commission's rules. This new service incorporates the existing Medical Implant Communications Service (MICS) "core" band at 402-405 MHz, and also includes two megahertz of newly designated spectrum in the adjacent "wing" bands at 401-402 MHz and 405-406 MHz. Altogether, the MedRadio Service will provide a total of five megahertz of contiguous spectrum on a secondary basis and non-interference basis for advanced wireless medical radiocommunication devices used for diagnostic and therapeutic purposes in humans. The MedRadio Service will accommodate the operation of body-worn as well as implanted medical devices, including those using either listen-before-talk ("LBT") frequency monitoring or non-LBT spectrum access methods, in designated portions of the 401-406 MHz band.

Significant advances in wireless implanted and body-worn medical technologies are revolutionizing treatment for a wide variety of medical conditions and, even more fundamentally, creating new health care models serving to improve quality of life for all Americans. As demonstrated by the record in this proceeding, implanted and body-worn medical devices that rely upon wireless technologies are being used even today to treat a variety of cardiac and diabetic conditions. For example, wireless implanted cardiac devices serve as defibrillators and pacemakers without the need for external wired connections; while other radio-equipped devices, such as blood glucose monitors and insulin pumps, support more timely treatment for diabetic patients and allow physicians to wirelessly retrieve data and then make operating parameter adjustments with greater ease and accuracy than with more traditional wired connection technologies. Some examples of newer generations of devices that could benefit from the use of wireless technologies include implanted vagus nerve stimulators that send electric pulses to the brain to treat severe chronic depression, and deep brain stimulators used to treat tremors related to Parkinson's disease. Such advances have the potential to significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions and, in turn, could result in lower medical costs and extend the time between hospital visits and surgical procedures.

A copy of the *Report and Order* available at http://hranufoss.fcc.gov/edocs_public/attachment/FCC-09-23Al.pdf (24 FCC Rcd 3474 (2009)).

2. General Information.

The new MedRadio service at 401-406 MHz will be governed under Part 95 of the Commission's rules, thus providing for license-by-rule operation throughout the 5 megahertz band. This approach minimizes regulatory procedures and will facilitate the more expeditious deployment of new generations of beneficial wireless medical devices in these bands that can improve the quality of life for countless Americans, thus serving the public interest, convenience and necessity. Furthermore, the operation of medical devices in the MedRadio band will be on a secondary, non-interference basis with respect to other authorized services and as such they must accept harmful interference from the systems operating in those services. MedRadio devices will operate on a shared, non-exclusive basis with respect to each other.

3. Requirements for a MedRadio medical implant device or MedRadio medical body-worn device.

In general terms, all MedRadio medical devices and associated transmitters must be used for the purpose of performing diagnostic or therapeutic functions in human patients.

Medical implant device or transmitter. In order to be classified as a medical implant transmitter or medical implant device, we will require that the transmitting antenna of the associated patient transmitting device must itself be implanted wholly within the body – which would include any point below the skin, or more

deeply within the body. We thus retain the former MICS definitions for medical implant devices. MedRadio devices falling into this category may operate across the entire 401-406 MHz MedRadio band pursuant to the technical rules for medical implant devices adopted by the Commission for the MedRadio Service.

Medical body-worn device or transmitter. In order to be deemed a *medical body-worn device* or *medical body-worn transmitter*, we will require that the antenna of the associated patient-worn device be placed upon or in very close proximity (*e.g.,* within a few centimeters) to the body. MedRadio devices falling into this category may operate only in the 401-402 MHz and 405-406 MHz wing bands, although an exception is provided in the MedRadio rules for certain body-worn devices that are temporarily used only for a short period of time in anticipation of installing a more permanent implanted device in a patient.

4. Eligibility requirements for operation.

Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MedRadio transmitters. Persons may also operate MedRadio transmitters to the extent the transmitters are incorporated into implanted or body-worn medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by or under the direction of a duly authorized health care professional. Manufacturers of medical devices that include MedRadio transmitters, and their representatives, are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MedRadio transmitter. The term "duly authorized health care professional" means a physician or other individual authorized under state or federal law to provide health care services. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

5. Certification requirements.

Each Medical Device Radiocommunication Service (MedRadio) transmitter (a transmitter that operates or is intended to operate in the MedRadio service) must be certified except for such transmitters that are not marketed for use in the United States, but which otherwise comply with the MedRadio Service technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. See 47 CFR § 95.603.

6. Certification procedures.

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, 218-219 MHz Service, LPRS, MURS, or MedRadio Service following the procedures in 47 CFR §2.907 and 47 CFR § 95.605.

7. Where can I find documents about the Medical Radio Service proceeding.

Investigation of the Spectrum Requirements for Advanced Medical Technologies,
ET Docket Nos. 06-135, 05-213, 03-92, RM-11271.

Report and Order – adopted 3/19/09; released 3/20/09
http://hranufoss.fcc.gov/edocs_public/attachment/FCC-09-23Al.pdf (24 FCC Rcd 3474 (2009)).

Notice of Proposed Rulemaking and Notice of Inquiry – adopted 7/13/06; released 7/18/06
http://hranufoss.fcc.gov/edocs_public/attachment/FCC-06-103Al.pdf (21 FCC Rcd 8164 (2006)).